

REQUEST FOR FEDERAL WAIVER OF STATE LICENSURE REQUIREMENT FOR PRESCRIPTION DRUG PLAN (PDP)

A. CORPORATE NAME: _____

(d.b.a.):_____

B. ADDRESS OF CORPORATION AND CONTACT PERSON

Corporation (Address)

(Not a Post Office Box)

Contact Person (Name and Address):

PHONE: (____) _____

(____) _____

FAX: (____) _____

(____) _____

C. REQUEST: We hereby request that the Secretary of the Department of Health and Human Services, pursuant to the authority granted under Section 1855(a)(2)(F) and Section 1860D-12(c) of the Social Security Act, grant a waiver of the requirement that our Prescription Drug Plan (PDP) sponsors be licensed under (Name State)_____ State law as a risk-bearing entity eligible to sponsor prescription drug benefits coverage.

D. CERTIFICATION: THE UNDERSIGNED OFFICER HAS READ THIS COMPLETED REQUEST FOR FEDERAL WAIVER FORM AND DOES HEREBY DECLARE THAT THE FACTS, REPRESENTATIONS, AND STATEMENTS MADE IN THIS FORM TOGETHER WITH ANY ATTACHED INFORMATION ARE TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE, INFORMATION, AND BELIEF. THE INFORMATION HEREIN DECLARED BY ME REPRESENT MATTERS ABOUT WHICH I AM COMPETENT, QUALIFIED, AND AUTHORIZED TO REPRESENT THE CORPORATION. IF ANY EVENTS, INCLUDING THE PASSAGE OF TIME, SHOULD OCCUR THAT MATERIALLY CHANGE ANY OF THE ANSWERS TO THIS REQUEST FOR FEDERAL WAIVER, THE CORPORATION AGREES TO NOTIFY THE CENTERS FOR MEDICARE & MEDICAID SERVICES IMMEDIATELY.

WITNESS/ATTEST

CORPORATE NAME:_____

By: _____

Name: _____
(Print Name)

Title: _____

E. INSTRUCTIONS (If you have any questions regarding this form please contact:

[Insert CMS Contact & Phone number]

Section A: Please enter your corporate name and the name under which your PDP will do business.

Section B: Please enter the street address, telephone number and facsimile number of the Corporation at its corporate headquarters and the name and address of a contact person.

Section C: Please indicate the State for which you are requesting a waiver.

Section D: Please have a duly appointed corporate officer sign this form in the presence of a witness.

F. NUMBER OF COPIES: Send 3 copies of this waiver request form to the following address:

[Insert CMS Address]

(THIS SECTION FOR OFFICIAL USE ONLY)

REQUEST FOR FEDERAL WAIVER OF STATE LICENSURE REQUIREMENT FOR PRESCRIPTION DRUG PLAN (PDP) Sponsors

I. BACKGROUND AND PURPOSE

This waiver request form is for use by Applicants who wish to enter into a contract with the Centers for Medicare and Medicaid Services (CMS) to become Prescription Drug Plan (PDP) sponsors and provide prescription drug plan benefits to eligible Medicare beneficiaries without a State risk-bearing entity license.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) generally requires Applicants who wish to become PDP sponsors to be licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant wishes to offer a PDP. However, the MMA created several exceptions to this State licensure requirement. These exceptions are similar to those applying to Provider Sponsored Organizations under the Balanced Budget Act of 1997.

In general, there are 2 types of waivers – both of which are more fully explained in Section II below. The waivers are: (1) Single State waivers. For these waivers, the Applicant should submit a separate waiver request for each State, and the waiver is effective only with respect to the single State. For applications submitted for plan years 2006 and 2007, special waivers are available as discussed more fully in Section II below. (2) Regional plan waivers. These waivers may be obtained if an Applicant is licensed in one State in a region and wishes to receive a waiver for all the other States in the region in which it is not licensed. In this case, the entity need only submit one waiver request – not one for each and every State in which it is not licensed.

Waiver requests should be submitted to CMS using the criteria described in the remainder of this paper.

Approval of a waiver request, in no way suggests, that the Applicant is approved for a Medicare contract with CMS. Following approval of a waiver request, the Applicant will be required to submit a Medicare contract application that demonstrates that the Applicant can meet the Federal definition of a PDP sponsor and that the prescription drug plan being offered will meet all plan requirements for PDPs.

Applicants who receive a waiver from State licensure must also comply with CMS standards for financial solvency and capital adequacy if they wish to receive a PDP contract.

II. WAIVER ELIGIBILITY

The following constitute the waivers available to Applicants. These are the sole grounds for receiving waivers. If you are applying for a waiver, please indicate the grounds upon which you are requesting a waiver (check all applicable areas):

A. SINGLE STATE WAIVERS

1. The State has failed to complete action on a licensing application within 90 days of the date of the State's receipt of a substantially complete application. 42 CFR 423.410(c)(1).
2. The State does not have a licensing process in effect with respect to PDP sponsors. 42 CFR 423.410(d).
3. For applications for plan years 2006 and 2007 only, the Applicant has submitted a substantially complete licensure application to each State for which it requests a waiver. 42 CFR 423.410(e).
4. The State has denied the license application on the basis of one of the following: (a) material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or (b) the State requires, as a condition of licensure, the Applicant to offer any product or plan other than a PDP. 42 CFR 423.410(c)(2).
5. The State has denied the licensure application, in whole or in part, for one of the following reasons: (a) On the basis of the Applicant's failure to meet solvency requirements that are different from the solvency standards developed by CMS; or (b) the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the information or documentation requirements in the solvency standards developed by CMS. 42 CFR 423.410(c)(3).
6. The State has denied the licensure application on the basis of grounds other than those required under Federal law. 42 CFR 423.410(c)(4).

B. REGIONAL PLAN WAIVERS

The Applicant is State-licensed in the State of _____ and is applying for a regional plan waiver in the following region: _____. 42 CFR 423.410(b)(1). The Applicant must demonstrate that it submitted a substantially complete licensure application in each State in the region for which it does not already have State licensure, except that no such application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

III. WAIVER DURATION

A. The Single State waivers listed in II.A. are effective for up to 36 months only and cannot be renewed unless CMS determines that the State in question does not have a licensing process in effect with respect to PDP sponsors. Thus, by the end of the three-year waiver period the PDP sponsor must be State-licensed if it wishes to continue as a PDP sponsor, unless CMS determines that the State in question has chosen not to create a licensing process for PDP sponsors – in which case the waiver can continue until CMS determines that a licensure process has been created. The special waivers for 2006 and 2007 will not be available for Applications submitted for 2008 and thereafter. Single State waivers automatically terminate if the PDP sponsor obtains State licensure.

B. The Regional Plan waivers expire at the end of the time period the Secretary determines is appropriate for timely processing of the licensure application, but in no case will a waiver extend beyond the end of the calendar year.

For both Single State and Regional Plan waivers, the waiver will terminate if the contract with Medicare terminates.

IV. INFORMATION TO BE INCLUDED IN THIS REQUEST

While the applicant should provide information concerning each of the following areas, the specific information and documentation requested below are not necessarily all inclusive for CMS to approve or deny the request. Applicants should provide any information and all documentation necessary to substantiate their request.

(a) Provide a written summary of the PDP entity or, if a line of business, a description of the entire organization. Also include information about management structure and the health care provider or group of affiliated health care providers that control the PDP. Discuss legal history, predecessor corporations, recent mergers or re-organizations, recent change-of-ownerships; any State licenses held, any previous or current contractual involvement with the Medicare program either directly with CMS or by contract with an HMO.

(b) Provide a narrative of the circumstances leading to the PDP's eligibility for a waiver based on one of the grounds listed in section II. Include information about the State risk-bearing entity license for which the PDP applied, the application process that the PDP followed, and any relevant interaction with the State.

(c) Provide documentation to substantiate the narrative required in (b). Depending on the grounds for waiver eligibility, this documentation should include but is not necessarily limited to the following:

1. Evidence of a State's failure to act on a licensure application on a timely basis

Copy of the dated cover sheet to the application submitted to the State, State confirmation of the receipt and completeness of the application, State requests for additional information, and all pertinent correspondence with the State relating to the status of the application, etc.

2. Evidence that Applicant submitted licensure application to the State (special 2006/2007 waiver)

Copy of cover letter to appropriate State authority that accompanied Applicant's licensure application.

3. Evidence of denial of the application based on discriminatory treatment

Copy of denial letter from the State, copy of "discriminatory" material requirements (including, State laws and regulation), procedures or standards to which the PDP was required to comply that are not generally applicable to other entities engaged in a substantially similar business, a copy of State licensure requirements that the PDP offer a particular product or plan in addition to a Medicare Advantage plan, and any supplemental material received from the State explaining their rationale for the denial, etc.

PDPs seeking a waiver on the grounds that they are subject to requirements, procedures and standards not applicable to entities engaged in a “substantially similar business” must demonstrate through submission of these and other appropriate materials:

- a) The types of entities subject to the different requirements, procedures and standards are engaged in a “substantially similar business”.
- b) The State requirements, procedures and standards imposed on the PDP entity are not applicable to other “substantially similar business” entities.

4. Evidence of denial of the application based on solvency requirements

Copy of denial letter from the State, copy of State solvency requirements, demonstration of the difference between State solvency requirements, procedures and standards and Federal PDP solvency requirements, procedures and standards, any other State information regarding documentation, information, and other material requirements, procedures or standards relating to solvency, or any correspondence detailing the reason the application was denied, etc.

6. Evidence of State licensure standards other than those required by Federal law

Memo identifying the State licensure standards by reference to relevant State law, regulation, or policy guidance and describing the how those standards differ from those required by Federal law.

7. Regional Plan Waiver

Evidence of licensure in one State within a regional plan and evidence that a substantially complete application has been submitted to the other States in the region – unless CMS determines that there is no PDP licensing process in effect in a State.

(d) Provide the name, address and telephone number of all State regulatory officials involved in the State application and/or denial proceedings.

(e) Please cite and describe any current PDP laws and/or legislation in the State.

(f) Briefly describe the proposed service area including counties and major cities. It is not necessary at this time to include maps. Note: if the organization plans on providing services in more than one State where it is not licensed, it will have to file a separate waiver request for each State.

(g) Provide any other information that you believe supports your request for a waiver under Section II.

V. OVERVIEW OF WAIVER REQUEST PROCESS

Section 1860D-12(c) and Section 1855(a)(2)(F) of the Act requires the Secretary to grant or deny this waiver request within 60 days after the date the Secretary determines that a substantially complete application has been filed. Upon receipt of a waiver request, CMS will review it to determine whether it contains sufficient information to approve or deny the request. The 60-day review period begins at the time CMS determines that the applications is substantially complete. For those applications deemed incomplete, CMS will work with the applicant to identify the remaining information necessary to either approve or deny the request.